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No. 86-1783

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In the Supreme Court of the United States

October Term, 1986

JERRY J. COLAHAN, d/b/a IBA OF OHIO, NORMAN F.
BAUER, JOHN D. BURROWS, RUSSELL C. HUMPHREY,
JR., SIMON E. MILLER, IBA, INC., DANIEL BELSITO,
Petitioners,

vs.

UNITED STATES OF AMERICA,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

PETITIONERS' REPLY BRIEF

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Typical of the bootstrap argument the Government has pursued throughout this action is the sentence on page 4 of its Opposing Brief:

Since 1938, the FDA has recognized that some animal drugs cannot be used safely except under a veterinarian's supervision, and that such drugs, by definition, cannot be labeled adequately for laymen's use.

No citation is given for that statement. In 1938, Section 503(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) did recognize the possibility of "prescription"

veterinary drugs; that is, veterinary drugs for which adequate directions for lay use cannot be written. However, that section was replaced with a new Section 503(b) as part of the Durham-Humphrey Amendments of 1951. The new language limited the prescription drug category to human drugs. As stated in Senate Report No. 946, 82nd Cong., 1st Sess. 8 (1951):

In limiting prescription drugs to those intended for use by man this new subsection differs from the present law, which refers to prescription drugs to include not only those dispensed on prescription of physicians and dentists, but also those dispensed on prescription of a veterinarian. Under the committee bill, drugs intended for use under the supervision of a veterinarian will not require a prescription, although it will be possible under Section 502(f) to exempt such drugs from adequate directions for use if they are to be used by or under the supervision of a veterinarian.

Section 502(f), 21 U.S.C. § 352(f) (Appendix "App." at A69), states that a veterinary drug is misbranded *unless* its labeling bears adequate directions for use. It includes a proviso that the FDA may promulgate regulations exempting drugs from adequate labeling if such labeling "is not necessary for the protection of the public health." In 1975, the FDA promulgated 21 C.F.R. § 201.105, which seeks to establish a prescription category for veterinary drugs that:

. . . because of toxicity or other potentiality for harmful effect . . . is not safe for animal use except under the supervision of a licensed veterinarian, and hence for which "adequate directions for use" cannot be prepared. . . .

App. at A77.

Faced, however, with the explicit language of Section 502(f) of the FDCA, the FDA historically recognized that any person charged with misbranding a veterinary drug on the basis of sale without a prescription could defend against the charge by proving that the drug contained adequate directions for lay use. *See, e.g., Classification of OTC and Rx Drugs*, CVM Staff Manual Guide No. 1240.2220; FDA's Brief in Opposition to Petition to this Court in the prior appeal of this case, Case No. 80-2067, p. 13, n.11. That was the only reasonable interpretation of Section 502(f), since that section limits the FDA's authority to promulgate regulations to veterinary drugs which do not require adequate directions for lay use. Further, 502(f) states that only drugs without adequate directions for lay use can be misbranded.

In this case, however, the FDA has done a turnaround, now claiming that 21 C.F.R. § 201.105 does obliterate the statutory defense of adequate directions for lay use. Specifically, as noted above, the FDA now claims that any veterinary drug which carries a prescription label is a toxic, unsafe drug for which adequate directions cannot be written.

The implicit assumption in the FDA's argument is that some adjudication occurs at some point during which competent authorities determine that adequate directions for lay use cannot be written for a particular veterinary drug and it is toxic and unsafe. The undisputed evidence is that no such adjudication is part of the approval process. The lack of any requirement that the veterinary drug be *found* to be unsafe without a prescription label precludes collateral use of the label alone to bar all of IBA's defenses. As summarized by Judge Jones in his dissent in the Court of Appeals:

Essentially the Government's position is that by virtue of bearing the cautionary label for New Animal Drug purposes these compounds have achieved the status of "prescription animal drugs" and, by that fact alone, they fall within Section 201.105 coverage. . . . [T]he collateral use of the NAD status of these drugs as proof that they are unsafe under Section 201.105 . . . relies on two possibly invalid assumptions: first, that the Secretary actually considered whether or not the drugs required the cautionary label and, if so, second, that the decision was based on a finding that the drugs were in fact unsafe without the label.

Sixth Circuit Opinion, App. at A18, A20 (footnote omitted). The FDA admits in its brief before this Court that veterinary drug distributors such as IBA have no opportunity to participate in the proceeding in which the "decision" to apply a prescription label is made. See Opposing Brief, pp. 3-4, n.2 where the Government admits that "the FDA's decision whether to approve a drug is not a public proceeding" that "the pendency of an NADA is confidential," and "only the sponsor can appeal the decision." Nor does the Government deny that the prescription label is voluntarily offered by the manufacturer of the veterinary drug to speed up the approval process. By so doing, the manufacturer avoids the necessity of providing expert testimony and clinical testing to support a claim that the drug contains adequate directions for lay use.

As a result, the party with absolutely no incentive to market a veterinary drug without the prescription label (the manufacturer) is the only party with a right to assert that the drug contains adequate directions for

lay use. On the other hand, a distributor or dealer who sells biologically equivalent veterinary drugs, one of which bears the manufacturer's voluntary prescription label and another which does not,¹ is precluded from defending a misbranding charge by proving that the prescription label is unnecessary because the drug contains adequate directions for lay use.

Such reasoning is wholly contrary to the law of this Court that due process cannot be trampled by the doctrine of collateral estoppel, as expressed in *United States v. Utah Construction & Mining Co.*, 384 U.S. 394, 422 (1966) and *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 319, 329 (1971).

At pages 10 and 11 of its Opposing Brief, the Government suggests a parade of horrors which would result if this Court were to enforce IBA's fundamental rights to defend against misbranding charges. These are illusory. First, veterinary drug distributors could not "at any time obtain de novo review in district court of FDA's determination regarding the prescription status of a drug . . .". Opposing Brief, p. 10. The distributor simply would be permitted to raise its traditional statutory defense, adequate directions for lay use, in a misbranding proceeding—an issue not addressed by the FDA in any factfinding proceeding. Second, sponsors of a New Animal Drug could not obtain de novo review. *Id.*, p. 11. By voluntarily offering to put the prescription label on the veterinary drug

1. For example, one of the veterinary drugs which the FDA alleged in its complaint to be a toxic "prescription" drug, and which was included in the injunction issued by the trial court, was later removed pursuant to stipulation by the Government that the same drug was also sold over-the-counter ("OTC"). Nevertheless, IBA was not permitted to defend this action on the grounds that other of the allegedly prescription drugs were sold OTC.

during the application process, the sponsor would have waived, or be estopped from raising, that claim. Finally, the "considerable uncertainty" which would allegedly be engendered by different federal courts considering individual defenses is neither greater nor worse than the uncertainty which inherently results when federal district courts fulfill their duty to enforce federal statutes.

Finally, the United States ignores the fact that two of the enjoined drugs are not NADA's, and thus did not even go through the truncated application process which the Government claims to be binding in this case. Judge Jones noted these discrepancies in his dissent, App. at A21-23.

In sum, the FDA has attempted, with a most dubious interpretation of its power to promulgate regulations governing veterinary drugs which do not require adequate directions for lay use, to create a "prescription" category for veterinary drugs. Historically, however, the agency has recognized that its regulation cannot go so far as to eradicate the statute's explicit defense that a veterinary drug which contains adequate directions for lay use is not misbranded. In this case, the FDA has assumed authority beyond that of the legislature or judiciary, in violation of fundamental due process limits on the use of collateral estoppel and contrary to the clear language of the statute. This Court should not allow summary injunctions against veterinary drug wholesalers, distributors, and dealers based on the collateral effect of a closed administrative proceeding in which no fact findings are made and in which the only party who can appeal the prescription label requirement not only has no incentive to appeal, but is encouraged to place a restrictive label on the drug voluntarily.

CONCLUSION

The Petition for Writ of Certiorari should be granted, the summary judgment and injunction vacated, and the case remanded to the trial court for trial on the defenses raised by IBA.

Respectfully submitted,

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